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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,203	09/23/2003	Michael P. Wallace	03-247 (US01)	2638

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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,203	WALLACE, MICHAEL P.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *4,5,9,14-17,22,23 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8,10-13,18-21,24,25 and 27-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-8, 10-13, 18-21, 24, 25 and 27-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken et al. (USPN 5,853,418) in view Bose et al. (USPN 6,605,111 B2).

Regarding claims 1, 6, 7, 10, 11, 18-21, 24, 25, 27, 28, 32, 33, 35 and 36, Ken et al. disclose a vaso-occlusive device for treating a site within a patient's vasculature, the device comprising a helically wound coil (coiled formed by 102 and its analogous counterparts in the other embodiments) forming a lumen and formed of platinum (see col. 4, lines 47-60), a filament/heating member (first material) (108, 208 and 214 and their analogous counterparts in the other embodiments) disposed in the lumen, the heating member at least partially comprising a first highly resistive, ferrous material (contains iron), the first material that is embedded within the device and which may be heated by application of a source of energy external to a patient's body after the device is implanted

at a treatment site in the patient's body, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D. Ken et al. fail to disclose a bioactive agent that is activated or released when the device is heated. Bose et al. disclose endovascular thin film devices and methods for treating and preventing stroke including polymerizing a polymer via a polymerization initiator in the form of radiation and heat energy, see col. 17, lines 38-61 and teach

> *"Where appropriate, bioactive agents can be incorporated in the devices. In this case, the precursor material that makes up the device is mixed with a bioactive ingredient and a biodegradable monomer which is also polymerized in situ to form the repair device. As the biodegradable polymer degrades, it releases the bioactive ingredient at the site of the device.*
>
> *Preferred polymers to mix with the precursors to form an endovascular thin film device which releases active ingredients are polyesters in the polylactide/polyglycolide family. These polymers have received a great deal of attention in the drug delivery and tissue regeneration areas for a number of reasons. They have been in use for over twenty years in surgical sutures, are Food and Drug Administration approved, and have a long and favorable clinical record. A wide range of physical properties and degradation times can be achieved by varying the monomer ratios in lactide/glycolide copolymers: poly-L-lactic acid (PLLA) and poly-glycolic acid (PGA) exhibit a high degree of crystallinity and degrade relatively slowly, while copolymers of PLLA and PGA, PLGAs are amorphous and are rapidly degraded. There are essentially no limitations on the bioactive agents that can be incorporated in the repair devices, although those material which can be processed into particles using spray drying, atomization, grinding or other standard methods, or those materials which can be formed into emulsions, microparticles, liposomes or other small particles, and which remain stable chemically and retain biological activity in a polymeric matrix, are preferred. Bioactive agents also include compounds having principally a structural role, for example, hydroxyapatite crystals in a matrix for bone regeneration. The particles may have a size of greater than or less than the particle size of the polymer particles used to make the repair device.*
>
> *Examples of such bioactive materials generally include proteins and peptides, nucleic acids, polysaccharides, lipids, and non protein organic and but not limited to, anti-inflammatories, inorganic compounds, referred to herein as "bioactive agents" unless specifically stated otherwise. These material have biological effects including, antimicrobials, anti-cancer, antivirals, hormones, antioxidants, channel blockers, and vaccines. It is also possible to incorporate materials not exterting a biological effect, such as air, radiopaque materials, such as barium, or other imaging agents.*

> *The bioactive agents can be incorporated in the devices by adding both the bioactive agent and the biodegradable monomer to the precursor prior to polymerizing the precursor in situ,"*

see col. 25, line 26 through col. 26, line 18. It should be noted the combination of Ken et al. and Bose et al. provides a polymer containing a bioactive agent/ingredient that is released upon the polymerization of the polymer vie the heating of the polymer. Therefore at time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ken et al., as taught by Bose et al. to provide the polymer with a bioactive agent in order to obtain various desirable results as noted above.

Regarding claims 2, 3, 12 and 13, Ken et al. further disclose a second material (polyethylene) having a melting or glass transition temperature greater than body temperature, but less than a temperature reached by the heating member when heated directly or indirectly by the external energy source and wherein the second material is embedded in one or more portions of the coil, such that, when heated by the heating member and allowed to cool in the body, the one or more portions are at least partially fused together to stabilize the coil in a deployed configuration, see col. 5, line 64 through col. 6, line 62 and figures 1A-2C.

Regarding claims 8 and 29, Ken et al. in view of Bose et al. disclose the claimed invention. It can be clearly seen that (108 and all analogous counterparts in other embodiments) of Ken et al. is embedded in the element, see figures 1A-10.

Regarding claim 30, Ken et al. in view of Bose et al. disclose the claimed invention.

Regarding claim 34, Ken et al. disclose the claimed invention, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D.

Response to Arguments

Applicant's arguments filed 6/12/2006 have been fully considered but they are not persuasive. The arguments/remarks directed to the 102 rejections since those rejections have been removed due to the amendments.

Regarding Applicant's arguments/remarks directed to the 103 rejections, Applicant asserts "there is no teaching or suggestion to provide a vaso-occlusive device comprising a first material which may be heated by application of a source of energy external to a patient's body, and a bioactive agent which is released or activated directly or indirectly upon such heating of the first material," see 3rd full paragraph on page 10.

First, the examiner has provided the passage line in Bose et al. that clearly discloses that although the polymer is biodegradable it is also polymerized (i.e. melted) by heat energy upon which it cools, releases the bioactive agent and begins to biodegrade.

Secondly, it is clear from Applicant own disclosure that heating the first material initially exposes a layer/portion of bioactive agent that is then released into the body simply because it is not shielded anymore, see page 8, line 22 through page 10, line 12 of the present application

specification. Therefore, Applicant has interpreted the heating and subsequent activation/release of the bioactive agent very broadly but in a manner consistent with Applicant's specification.

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.R. A.R.
August 14, 2006

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER